

§ 73.2150

are cosmetics subject to the following conditions:

(1) It shall not be used at a level in excess of 0.1 percent.

(2) It may be used only in combination with the following substances:

Water.

Glycerin.

Sodium carboxymethylcellulose.

Tetrasodium pyrophosphate.

Sorbitol.

Magnesium phosphate, tribasic.

Calcium carbonate.

Calcium phosphate, dibasic.

Sodium *N*-lauroyl sarcosinate.

Artificial sweeteners that are generally recognized as safe or that are authorized under subchapter B of this chapter.

Flavors that are generally recognized as safe or that are authorized under subchapter B of this chapter.

Preservatives that are generally recognized as safe or that are authorized under subchapter B of this chapter.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.2150 Dihydroxyacetone.

(a) *Identity and specifications.* The color additive dihydroxyacetone shall conform in identity and specifications to the requirements of § 73.1150 (a)(1) and (b).

(b) *Uses and restrictions.* Dihydroxyacetone may be safely used in amounts consistent with good manufacturing practice in externally applied cosmetics intended solely or in part to impart a color to the human body.

(c) *Labeling requirements.* The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the requirements of section 721(c) of the act.

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§ 73.2162 Bismuth oxychloride.

(a) *Identity and specifications.* (1) The color additive bismuth oxychloride shall conform in identity and specifications to the requirements of § 73.1162(a)(1) and (b).

(2) Color additive mixtures of bismuth oxychloride may contain the following diluents:

(i) For coloring cosmetics generally, only those diluents listed under § 73.1001(a)(1);

(ii) For coloring externally applied cosmetics, only those diluents listed in § 73.1001(b) and, in addition, nitrocellulose.

(b) *Uses and restrictions.* The color additive bismuth oxychloride may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

[42 FR 52394, Sept. 30, 1977]

§ 73.2180 Guaiazulene.

(a) *Identity.* (1) The color additive, guaiazulene, is principally 1,4-dimethyl-7-isopropyl-azulene.

(2) Color additive mixtures of guaiazulene for cosmetic use may contain the following diluent:

Polyethylene glycol-40 castor oil (PEG-40 castor oil).

Saponification No., 60 to 70.

Hydroxyl No., 63 to 78.

Acid No., 2.

Specific gravity, 1.05 to 1.07.

(b) *Specifications.* Guaiazulene shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice.

Melting point, 30.5 °C to 31.5 °C.